Role of External Factors on Export Potential of Pakistan Pharmaceutical

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Abstract

The report aims to discuss the external factors effecting export's potential of Pakistan's pharmaceutical industry by conducting a survey through questionnaire by applying the quantitative research methodology. The research revealed that the export of pharmaceutical has a lot of potentials to add to the GDP of Pakistan. However external factors like Pakistan Government export regulation and policies, DRAP Policies, International regulatory compliances, Drug registration in export market and Standardization in licensing are challenges for local and international companies' sales and growth. Through both qualitative and quantitative analysis of various perceptions and experiences of Pakistan's pharmaceutical manufacturers concerning an export trade in other countries. Study indicate that by far, the most significant barrier to trade is considered to be the absence of an effective regulatory environment in Pakistan. This has translated in a lack of transparency, with no clearly defined pricing mechanism, DRAP Policies, week standardization in licensing and registration structure and absence of international regulatory compliance may create environment for industry to grow slow and high risk faced.

Keywords*: Export potential, Pakistan Government export regulation and policies, DRAP Policies, International regulatory compliances, Drug registration in export market, Standardization in licensing.*

1 INTRODUCTION

Pakistan has vigorous and enlightened Pharma industry. Pakistan came into being in 1947, at that time country had hardly any Pharma industry. Now it has more than 400 Pharma companies in which 25 units operated by multinational present. These companies are able to fulfil 70% demand of finished goods of country. Market share, for domestic pharma is nearly equal divided among national and multinational (Ahmed, R.R., &Saeed, A., 2012). In Pakistan Pharmaceutical market is developing with the rise in population and economic growth. But spending on drug per capita is low that is US$9.30 in 2007 (Ahmed, R.R., &Jalees, T. , 2008). In the international market, as a Pakistan is stepping forward with export turnover of over US$ 100 Million in 2007. Many units of industry have been accepted internationally due to its quality producers and regulatory authorities. As compare to domestic market, sales recorded double in last five years in international market. Pharmaceutical industry is focusing on export by spreading their presence in new region and clear vision of gripping global opportunities (Ahmed, R.R., &Saeed, A., 2012). However, industry is facing lots of issues, including external factors like Government export regulation and policies, DRAP Policies, International regulatory compliances, Drug registration in export market and Standardization in licensing effecting of potential of export.

1.1 Research Aim

The report aims to discuss the role of external factors on export potential of Pakistan's pharmaceutical industry by conducting a survey through questionnaire by applying the quantitative research methodology.

1.2 Research Objectives

Following are the main objectives of research such as;

1. To evaluate the external factors effecting on export of Pakistan Pharmaceutical industry

2. To analyse the challenges faced by the export pharma sector of Pakistan
3. To evaluate the external factors effects on GSK's export of Pakistan

2 LITERATURE REVIEW

Pakistan Pharma industry is showing continuous growth in pharma industry sector over the years. The industry is showing development by investing to upgrade the system and mostly companies are using Good Manufacturing Practices (GMP), under domestic as well as international guidelines. Country is currently enable to produce simple pills to advance biotech, and generic compound as well (Aamir, M., &Zaman, K., 2011). Pakistan's population is around 170 million people make it most populous country, having GDP US$284 billion, having worth is US$2.29 million with annual growth rate of 5.8% in 2019. The 2/3rd market share hold by national companies and 1/3rd hold by multinational companies. (IMS, 2011) The imported portion is 1/3rd of total consumption of Pakistan.

Despite the rapid expending and progress in pharma industry and health care sector, in Pakistan half the population and deprived of modern medicine (Ahmad, M., Akhtar, N., Awan, M.H.A., & Murtaza, G., 2011). The government of Pakistan invested US$133 million in pharmaceutical industry since 1999, as of today it has more than 800 national pharmaceutical units including 25 multinational present. Pharmaceuticals exports with the help of government, to several Middle-Eastern and African countries. Although Pakistan face decline in export from middle income countries but during 1980-1999, export was doubled from 1.1% to 2.9% (WHO, 2004). Over the year's Pharmaceutical value increased.

2.1 Health Sector and System

In Pakistan, system of healthcare sector is very well organized, but being developing country some natural issues cannot be ignored. The pharmaceutical industry can be divided into public and

private sector, Public sector provides healthcare service largely with the government aids, whereas private sector run on more commercial ways. The Government expenditure on healthcare sector is low roughly around 3.2% of the GDP, very less than other socioeconomic countries like Bangladesh and Sri Lanka. The expenditure on health 78% are out of pocket (Shaikh, B.T., &Hatcher , J., 2007). The authority is transfer from central to local with the responsibility of government at the provincial level mainly for public sector. The six health programs on immunization, family planning, tuberculosis, HIV/AIDS, malaria, and nutrition are looking after by the central ministry of health due to national policy and design (PSLM, 2005–2006).

Public sector is lack of essential medical services like professional staff, vital drugs and medical supplies, this situation force patient seek medical treatment in private sector due to government expenditure are 70% out of the pocket in Pakistan (WTO, 2009). The healthcare system mainly operated in urban region, with private sector dominancy, create difficulties for rural region. People are looking for medical treatment in private sector or other source largely as per Pakistan Social and Living Standards Measurement Survey (PSLM, 2005–2006).

2.2 National Health Policy

The National health policy was established in 2001, having clear goal for healthcare services to all. The policy main function to develop strategies for the health sector, having main objective of policy is to invest in health sector part of the government's Poverty Alleviation Plan, in which primary and secondary level healthcare facilities given priority so that further third level facilities load can be eliminated. For milestone achievement in quality field good governance structure is anticipated in the policy. The policy highlighted key areas like decreasing of transmissible diseases, administrative incompetence and third level healthcare facility reduction, provide gender

equity, increase health of population by providing quality nutrition scheme, bring improvement in public and rural areas and overall health policy, procedure and its implementation (Policy, 2001).

2.3 National Drug Policy

A national health policy (NDP) plays vital role in protections balanced access to and comprehensible usage of anodyne and effective drugs. The ministry of health form NDP, under the sanctions of World Health Organization (WHO), drug action program held in 1997. In which eight essential objectives highlighted, including polices about essential drugs supply, promotion, development, prevention of inappropriate and substandard drugs usage for public health enhancement, self-reliance in drugs achievement by promoting local source of raw material, acquire and develop trained workforce for management, improve R&D department and overall work for pharmaceutical industry growth. The policy work for two main areas, endorsing the pharmaceutical industry and encouraging and caring public health, by facing and solving all types of issues, challenging, and conflict of interest (Policy, 2009).

2.4 Regulatory issues (registration/inspections)

The Ministry of Health, Drug Control Organization (DCO), has the core accountable for operating the pharmaceutical sector in Pakistan. The DCO act and function as per Drugs Act 1976 and its policies. It has three main units under the control of drug controllers are Registration, Quality Control, and R&D. Drug controllers is considered as the technical head and director general is act as a departmental head. Provincial headquarters monitor and implement the manufacturing licenses and practices of drugs basically are field offices. The provincial governments' inspectors appointed for post marketing practices and looks after sale of medicine in all provinces at tehsil and district levels. (MOH, 2010) Drug Regulatory Authority of Pakistan (DRAP) Act 2012,

established to enhance the effectiveness of managing Drugs Act 1976 (XXXI of 1976). This action leads stepping toward trade and commercialization drug product inter conditionally.

2.5 Drugs Act

In Pakistan sale of drugs monitored in accordance of Drug Act 1940. The concept of Generic Names Act of 1972 was established by the government in 1972. This act forces the manufacture to produce, distribute and sale drugs under generic names only. But this act was not implemented due to multinational pharmaceutical companies' pressure. An inclusive drug act was established in 1976, and implemented by the government after approval. The act called Drug Act of 1976, and controlled over registration, license, production, marketing and quality control, and R&D of drugs in the country (MOH, 2010).

2.6 Export in Pakistan's Pharmaceutical industry

In Modern area, mostly countries are focusing on the development of their pharmaceutical industry, for getting self-reliance, availability of medicine and revenue generation through export. Despite that only few literatures discourse pharmaceutical industry's growth and its dynamic effect and relationship with public health. As an example in India, pharmaceutical industry has been grow rapidly, but despite this fact only 35% access to essential drugs. In India unreasonable prescribing and fake drugs available largely which cause huge problem and further market is not regulated effectively. Due to this situation, it is a very questionable situation that further pharmaceutical industry's international growth might benefit its' millions of poor people (Malhotra, P., &Lofgren, H. , 2004).

Country like China, Brazil and India are developed countries, but still exporter of medicine of these countries import to certain pharmaceutical finished good, or ingredients to provide base to their export and as per USA report published in 2005, at the Boston University of Public Health

by Kaplan and R Laing, local production policies are quite basic and self-reliance is based on illusion and ingenuous (Kaplan, W., &,Laing, R., 2005).

A world bank observed and reported that, local production of some countries face economies of scale and advance technology issued so unable to make any economic sense. But this situation is quite opposite for certain countries like china, India, Egypt etc. producer of these countries have capacity to produce huge amount of active ingredients of pharmaceutical (Lashman, K., 1986).

Kaplan W and Laing R 2005 discussed in their report about Pakistan, large domestic of this country market play a vital role in local production success. The government of Pakistan, is actively supporting and focusing pharmaceutical industry, and has taken some major steps like giving target to its Health Minister to export for generating revenue. But some areas policies like prices, basis use of drugs and its access is not clear. There is huge ambiguity exit regarding prices should be decreased and affordability need to be improved or promotion of rational and ethical drug use decreased? As compare to Pakistan, Malaysia has established very good drug regulatory structure and gain lot of improvement in national medicine policies. However, county is still facing issues like, promotion of inexpensive generic drugs, self-support, awareness of usage of medicine to consumer and high cost of medicines. For resolving these public issues pharmaceutical industry turned into a giant player economic by government agencies (Anon, 2006).

2.7 Registration and standardization in licensing in Pakistan:

The Pharmaceutical industry face disapproval and questioned for availability of counterfeit drugs in the market by the government and people it’s even down the quality graph of pharmaceuticals. In 2002, Forum Europe reported that 50% Cigar, medicines forged in Pakistan in scenario of Global Healthcare and Development issue. With the rise in local production, similar named products are available in market too often create ambiguities for doctors and pharmacists. This was

reported in an unpublished paper under title of Registering Confusing Medicine Names: An Unchecked Practice Affecting Public Health in Pakistan' in 2006 by A Hussain and ZU Babar.

In Pakistan noncompliance with Good Manufacturing Practice, quality of medicine is highly concern. Pharmaceutical manufacture highlighted GMP and procedure used in making oral tablets represent quality of APIs (Rehman, H., 2010). Rules of Licensing, Registering and Advertising of drugs for GMP requirement presented in 1976 in Pakistan which is not updated timely (Zaidi, S.Bigdeli, M., Aleem, N., &Rashidian, A., 2013). This means that international guidelines or WHO rules and regulation updated in current registration process (W.H.O, 2016).

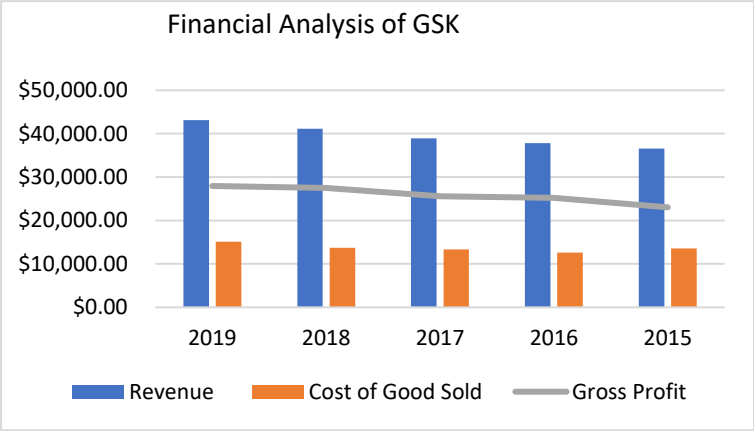
More than 80,000 drugs registered in Pakistan, over this registration few physicians concern over protection and effectiveness of generics drugs low in cost, result prescribing originator products in country highly (Jamshed, S.Q., Hassali, M.A., Ibrahim, M. I., &Babar, Z.U., 2011). This condition is affecting low income public in term of affordability Glassman 2006. Further compromises cannot be done on quality of medicine can concern over generic antirejection medicine need to be reduce (Godman, B. &Baumgärtel, C., 2015).

APIs of registration of raw material of drugs in Pakistan is currently not efficient and have concern on system. Registration process need to be updated as per international, WHO and ICH recommended CTD format so that quality and export potential can be improved. WHO present proper guideline for registration process that help Pakistan's current system. It will not increase standard, cost-effective generics and protection of medicine within country but other region as well (Khan, B. Godman, B., Babar, A., Hussain, S., Mahmood, S., &Aqeel, T., 2016). Soon CDT format will implement in Pakistan for online registration for paperless and efficient registration in Pakistan and meet international standard.

Pakistan current licensing system doesn't fulfill international standard, and limited ability to manufacture finished good and APIs at the same time. Current licensing system has majors issues of consistency, reliability, clearness, liability and monitoring vary on GMP inspections. Pharmaceutical industry manufacture with GMP compliance are at great risk for export point of view. For achieving PIC/s membership, strong system is required for controlling and implementation of all activities and product life cycle, progressive licensing system introduced on the basis of risk management (DRAP, 2020). Through this system, license will be issued that enforce licenses holder to fulfil all GMP, QMS with ICH guidelines elements. Further inspection system and recording setup has been updated as per international standard.

Further to understand the effect of external factors on GSK has been taken as case study for the research paper. GlaxoSmithKline Pakistan Limited was established in Pakistan on January first, 2001 through the merger of SmithKline and French of Pakistan Limited, Beecham Pakistan (Private) Limited and Glaxo Welcome (Pakistan) Limited and stands today as the biggest pharmaceutical organisation in Pakistan (GSK, 2019). GSK is a since a long time ago settled financial specialist in Pakistan. GSK is the leading brand operating in Pakistan and the only pharmaceutical firm to have its sales crossed the threshold of Rs10 billion, which is surely an outstanding achievement for GSK. GSK sales increased 10.81% in 2019 from 2018, with increase in gross profit 1.76% in 2009 which is decline as compare to 2018, as gross profit increased 7.41% as compare to 2017 (GSK, 2019). The growth rate is slower, export is only 3-4% of total sales of GSK due to currently, industry is facing challenges like Patent expiries, regulatory compliance issue and tremendous pressures from healthcare providers provide an environment which is responsible for to company's lower growth and high risk (ESSAY, 2018).

	2019	2018	2017	2016	2015
Revenue	$43,100.48	$41,139.87	$38,903.72	$37,797.96	$36,578.27
Cost of Goods Sold	$15,147.86	$13,699.69	$13,328.77	$12,590.74	$13,536.24
Gross Profit	$27,952.62	$27,470.18	$25,574.95	$25,207.22	$23,042.03



3 RESEARCH METHODOLOGY

For the research paper, Secondary data has been collected through literature review, journals and articles whereas primary data has been collected through questionnaire paper and interview. For questionnaire filling sample size of 300, from pharmaceutical industries has been selected, out of which 270 questionnaire filled out.

3.1 Research Hypothesis

The main hypothesis of research paper is **H1:** External factors are significantly effecting on export potential of GSK of Pakistan.

Based on the secondary data below variables have been discover to determine the significance on export potential of Pakistan Pharmaceutical industry. On the basis findings variables below hypothesis created. For clear understanding and analysis of significance of external factors, hypothesis of each variable developed, as listed below.

H1a: Pakistan government export regulation and policies are significantly effecting on export potential in the Pharmaceutical industry of Pakistan.

H1b: DRAP Policies are significantly effecting on export potential in the Pharmaceutical industry of Pakistan.

H1c: International regulatory compliances are significantly effecting on export potential in the Pharmaceutical industry of Pakistan.

H1d: Drug registration in export market is significantly effecting on export potential in the Pharmaceutical industry of Pakistan.

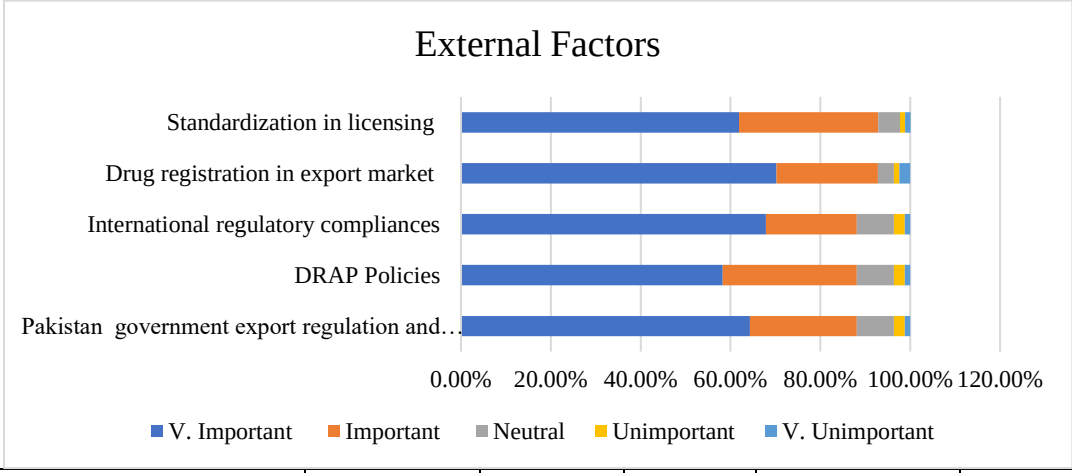
H1e: Geo political influence is significantly effecting on export potential in the Pharmaceutical industry of Pakistan.

H1f: Standardization in licensing is significantly effecting on export potential in the Pharmaceutical industry of Pakistan.

4 RESULT

Based on the questionnaire response data has been sort out on the percentage basis.

Table 01:



External Factors	V. Important	Important	Neutral	Unimportant	V. Unimportant
Pakistan government export regulation and policies	64.3%	23.8%	8.3%	2.4%	1.2%
DRAP Policies	58.3%	29.8%	8.3%	2.4%	1.2%
International regulatory compliances	67.9%	20.2%	8.3%	2.4%	1.2%
Drug registration in export market	70.2%	22.6%	3.6%	1.2%	2.4%
Standardization in licensing	61.9%	31.0%	4.8%	1.2%	1.2%

As per Table 1 and graphically presentation shows there is a positive relationship between dependent variable that is export potential and independent variables as majority of respondent marked them very important and important as, Pakistan government export regulation and policies (64.3%), DRAP Policies (58.3%), International regulatory compliances (67.9%), Drug registration in export market (70.2%), and Standardization in licensing (61.9%). Therefore, all hypothesis is accepted, thus due to acceptance of all variables, main hypothesis is also accepted.

H1: External factors are significantly effecting on export potential of GSK of Pakistan. (Accepted)

4.1 Interview Summary:

Interview was conducted from Mr. Akhlaq, Pharmacist by profession and hold Pharm D degree from Karachi University and MBA frok IBA, Karachi. He has overall 15 years of work experience in pharmaceutical industry. Currently, he is working for GSK Saudi Arabia as Quality Director and have prior work experience for the same company in Pakistan in various functions.

In my opinion, registration of your product and acquiring the trust of regulators of export markets is the most important factor for entering into export market. The registration process in most export markets is designed to take care of other key factors such as GMP, product quality and price of the medicine. All regulator either rely on the manufacturer's cGMP certifications to assess the current Good Manufacturing Practices or conduct the audit of manufacturing site and issue a GMP certificate of their own. Examples of GMP certificates are ISO certifications, US-FDA & WHO certifications. Many export markets trust US-FDA and WHO. If Pakistan Pharma manufacturers acquire GMP certifications from these authorities (US-FDA & WHO), they shall be able to export to most Global markets without further audits. However, it must be kept in mind that US-FDA holds the highest requirements and satisfying those requirements increase the cost of production.

Therefore, it depends upon the intent of manufacturer, if they are willing to go global for their export, they may go for GMP certification from US-FDA or WHO but if they have limited scope for export, they may option for GMP inspections from individual regulators.

5 CONCLUSION

Drug regulation has deficiency in persistent policies which created a gap between health sector and pharmaceutical industry. Government intervention is required as more funding is required in healthcare sector. Pakistan export regulation policies, drug registration policies must be viewed and upgraded as international regulatory compliance. The implementation of WHO regime for Pharmaceutical sector, ICH and CDT format improve the process and standard of pharmaceutical industry. The Government of Pakistan has taken some initiatives likes establishing investigation, bioequivalence and testing laboratories, and regulatory policies as per WHO guidelines. New online system for licensing must be adopted as per international which fulfil all GMP, QMS with ICH guidelines elements. Thus, the studies found that external factors like lack of government policies, week role of DRAP, absence of international compliance, slow registration process and standardization in licensing are effecting export potential of pharmaceutical industry.

Studies also found that inflexible pricing policy and inconsistency in government policies are significant challenges for GSK Pakistan. Further lack of international compliance, week registration and standardization in licensing process and frailer in DRAP policies may result in increase in low quality, low price and forged medicine available easily in Pakistan which effect ultimately GSK and other international companies. Further price freeze of product and low margin may increase risk of production, which hit sales at domestic and export level. Thus, hypothesis H1: External factors are significantly effecting on export potential of GSK of Pakistan is accepted.

6 RECOMMANDATION

It is recommended that Pakistan government need to develop independent drug regulatory authority department, free for all political interference, and managed professionally. Further it must adopt an international, WHO policies for regulating drug system of Pakistan, so that not only public and private health sector standard improved but also it helps exporter to compete internationally. It is also recommended that all the practice regarding marketing and promotion tool build effectively for behavioral changes among healthcare institutions.

Intensive care has been ensured during collection of primary and secondary data, all the variables currently significantly effecting and nature of these variables may change in future with introduction and implementation of new policies and system, yet more research in this area required for future studies.

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